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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/757,632 | 01/11/2001 | ChangSheng Liu | 9046-037 | 8188 |

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| EXAMINER | |
|---|---|
| DIAMOND, ALAN D | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1753 | |

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/757,632 | LIU ET AL. | |
| | Examiner | Art Unit | |
| | Alan Diamond | 1753 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 April 2004 and 25 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Comments*

1. The objection to the abstract has been overcome by Applicant's amendment thereof.

2. The indication of allowable subject matter in claim 3 is withdrawn by the Examiner in light of the rejections set forth below.

3. The rejections of claim 4 under 35 USC 102(b) over JP '575 and Novotny et al have been overcome by Applicant's amendment thereof to recite the injecting and applying steps.

### *Specification*

4. The amendment filed February 25, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In the paragraph beginning at page 2, line 18, the recitation of "+210 kV/cm" for the voltage applied across the capillary ends is not supported by the disclosure, as originally filed. The "kV/cm" appears to be the wrong unit, and it is not clear how the +210 was obtained.

Applicant is required to cancel the new matter in the reply to this Office Action.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At line 2 in each of claims 10 and 15, the "+210 V/cm" is not supported by the specification, as originally filed.

In claim 11, at each of lines 5 and 12, the term "liquid detergent" is not supported by the specification, as originally filed. The same applies to dependent claims 12-15. In particular, said term appears in claim 12 at line 5, and in claim 13 at line 5.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al, Journal of Chromatography A, 717, (1995), pages 33-39, in view of Petersen et al (U.S. Patent 5,792,330) and Wang (U.S. Patent 5,124,020).

In section 3.2 at page 35, Hu et al performs a capillary zone electrophoresis with a sample buffer having an SDS concentration of 35 mM. On page 36, at the first paragraph of the first column, another capillary zone electrophoresis is performed using an SDS concentration of 3.5 mM in the sample buffer. Between runs, the capillary was

rinsed with NaOH, and multiple runs were performed (see page 35, section 2.5). Hu et al teaches the limitations of the instant claims other than the differences which are discussed below.

The instant claims call for not using an NaOH intermediate rinse, whereas Hu et al uses such a rinse. However, Hu et al is not limited to NaOH for the rinse. Petersen et al teaches capillary electrophoresis, where NaOH or KOH can be used interchangeably for the rinse (see col. 16, lines 34-35 and 57-58). Wang teaches capillary zone electrophoresis wherein KOH is used for the rinse (see Example 3 at cols. 7 and 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used KOH in place of NaOH so as to perform Hu et al's rinse because NaOH and KOH are known alternatives in the art for rinsing, as shown by Petersen et al; and KOH can be used for rinsing in capillary zone electrophoresis, as shown by Wang.

Hu et al does not specifically recite "adding" the SDS to the sample to be electrophoresced. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added to have added the buffer containing the SDS to Hu et al's sample to be electrophoresced so that a sample that is ready for analysis could be obtained.

With respect to claims 10 and 15, Hu et al illustrates a voltage ratio of 17.5 kV/50 cm (i.e., 350 V/cm) (see section 2.5 at page 35), whereas said claims call for 210 V/cm. However, Hu et al is not limited to 350 V/cm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected an

appropriate column length and voltage so that the capillary zone electrophoreses could be performed. Nothing unexpected has been demonstrated using 210 V/cm as opposed to any other ratio.

9. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kenndler et al, Journal of Chromatography, 545, (1991), pages 397-402, in view of Petersen et al (U.S. Patent 5,792,330) and Wang (U.S. Patent 5,124,020).

Kenndler et al performs capillary zone electrophoresis using protein samples containing SDS at a concentration of 0.05% by weight (i.e., 1.7 mM) and 0.1% by weight (i.e., 3.5 mM) (see page 398; and Figure 1 at page 399). The buffer was borate (see page 398). Kenndler et al uses a sodium hydroxide rinsing steps (see page 389). Kenndler et al teaches the limitations of the instant claims other than the differences which are discussed below.

The instant claims call for not using an NaOH intermediate rinse, whereas Kenndler et al uses such a rinse. However, Kenndler et al is not limited to NaOH for the rinse. Petersen et al teaches capillary electrophoresis, where NaOH or KOH can be used interchangeably for the rinse (see col. 16, lines 34-35 and 57-58). Wang teaches capillary zone electrophoresis wherein KOH is used for the rinse (see Example 3 at cols. 7 and 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used KOH in place of NaOH so as to perform Kenndler et al's rinse because NaOH and KOH are known alternatives in the art for rinsing, as shown by Petersen et al; and KOH can be used for rinsing in capillary zone

electrophoresis, as shown by Wang. Furthermore, the application of third and fourth samples, after rinsing with the KOH, would have been within the skill of an artisan.

Kenndler et al does not specifically recite "adding" the SDS to the protein sample to be electrophoresced. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added to have added the buffer containing the SDS to Kenndler et al's protein sample to be electrophoresced so that a sample that is ready for analysis could be obtained.

With respect to claims 10 and 15, Kenndler et al illustrates a voltage ratio of 350 V/cm (page 398), whereas said claims call for 210 V/cm. However, Kenndler et al is not limited to 350 V/cm. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have selected an appropriate column length and voltage so that the capillary zone electrophoreses could be performed. Nothing unexpected has been demonstrated using 210 V/cm as opposed to any other ratio.

***Response to Arguments***

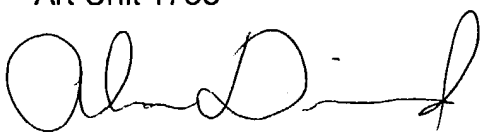
10. Applicant's arguments with respect to the instant claims have been considered but are moot in view of the new ground(s) of rejection.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alan Diamond whose telephone number is 571-272-1338. The examiner can normally be reached on Monday through Friday, 5:30 a.m. to 2:00 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alan Diamond
Primary Examiner
Art Unit 1753



Alan Diamond
April 29, 2004